AMENDMENT TO
BROAD AGENCY ANNOUNCEMENT FOR THE ADVANCED RESEARCH AND DEVELOPMENT OF CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR (CBRN) MEDICAL COUNTERMEASURES FOR
BARDA

Broad Agency Announcement (BAA) Number: BAA-16-100-SOL-00001
Amendment Number: 0005

A. SUMMARY OF CHANGES

This amendment revise the language to CBRN BAA Area of Interest #5 follows:

From:

Area of Interest #5: Chemical Threat Medical Countermeasures

Area of interest #5 includes medical countermeasures that protect the civilian population from the acute health effects of chemical threats, are easy to administer in a mass-casualty situation, and are rapidly effective as post-exposure therapies. The medical countermeasures (MCMs) should also be safe and effective for the entire population, including infants, children, adolescents, elderly, pregnant women and immunocompromised individuals. The technical readiness level for candidates should be at TRL 4 (i.e. completed all activities described for TRL 4) or higher; in vivo activity and potential for efficacy consistent with the product's intended use (i.e. dose, schedule, duration, route of administration, and route of threat agent challenge) must be demonstrated. Offerors should have submitted a pre-IND package to the FDA for licensure as an MCM prior to the submission of a white paper to the BARDA BAA. Specific areas of interest within Chemical Threat Medical Countermeasures include:

5.1 Nerve Agents:

5.1.1 Development of an antiseizurogenic that can stop seizures at extended times after onset, and/or when the seizures may have become refractory to current drugs.

5.1.2 Development of an improved acetylcholinesterase reactivator to replace pralidoxime chloride (e.g., broad spectrum; centrally acting)

5.1.3 Development of an improved anticholinergic to supplement atropine (longer acting and centrally acting).

5.1.4 Development of new formulations of existing antidotes (more easily

administered; faster acting).

5.2 Pulmonary Agents: Development of medical countermeasures, including anti-inflammatory drugs, to prevent and treat lung damage from exposure to agents such as chlorine and phosgene.

5.3 Vesicants: Development of medical countermeasures that limit harmful aspects of exposure to vesicating agents such as sulfur mustard and Lewisite, including topical (skin and eye) and systemic preparations.

5.4 Blood/Metabolic Agents: Development of MCMs to treat acute poisoning from agents such as cyanides and fluoroacetates. Antidotes should be easily administered by first responders and safe in all populations.

5.5 Toxic Industrial Chemicals and Emerging Threats: Development of individual MCMs (therapies) that can be used to treat the effects of multiple chemical threat agents and unconventional threats in response to new population threat assessments.

5.6 Development of easily administered and rapidly effective countermeasures that can be used by first responders dealing with large numbers of exposed individuals. Ease of administration in mass casualty situations should take into account the practical limits of injected medications versus inhaled, intranasal and sublingual administration. These alternative routes may fail if persons have profuse respiratory secretions. Autoinjector intramuscular injection may continue to be a preferred route of administration in many, but not all, circumstances.

5.7 Development of chemical decontamination solutions for use on intact /or injured human skin (improved efficacy compared to soap and water). Proposed solutions must be safe for whole-body use and amenable to use in a mass-casualty situation.

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To:

Area of Interest #5: Chemical Threat Medical Countermeasures

Area of Interest #5 includes medical countermeasures (MCMs) that treat the acute health effects of chemical threats, are easy to administer in a mass-casualty situation, and are rapidly effective as post-exposure therapies. The MCMs should be safe and

effective for the entire population, including infants, children, adolescents, elderly, pregnant women and immunocompromised individuals. The technical readiness level for candidates should be at TRL 4 (i.e. completed all activities described for TRL 4) or higher; in vivo activity and potential for efficacy consistent with the product's intended use as an MCM against a threat agent (i.e. dose, schedule, duration, and route of administration)) must be demonstrated. Offerors should have held a pre-IND meeting with the FDA for licensure as an MCM prior to the submission of a white paper to the BARDA BAA. Strong preference will be given to drug candidates that are already approved or are in clinical development for a conventional indication similar to that arising from exposure to a chemical agent. Specific areas of interest within Chemical Threat Medical Countermeasures include:

5.1 Pulmonary Agents: Development of MCMs to prevent and treat lung damage (including pulmonary edema and fibrosis) resulting from exposure to agents such as chlorine and phosgene.

5.2 Vesicants: Development of MCMs that limit harmful aspects of exposure to vesicating agents such as sulfur mustard and Lewisite. Needs include MCMs designed to treat lung, skin, and ocular as well as systemic effects.

5.3 Blood/Metabolic Agents: Development of MCMs to treat acute poisoning from agents such as cyanides. Antidotes should be easily administered by first responders in personal protective equipment. Preference is given to those cyanide antidotes that are also effective against smoke inhalation-related exposure.

5.4 Nerve Agents and OP Pesticides: Development of MCMs to treat seizures that are refractory to treatment with benzodiazepines. These drugs, in most cases, will be used after benzodiazepine therapy has failed.

5.5. Novel MCM Delivery Mechanisms: Development of improved methods of administration for new and existing MCMs. The candidates should be amenable to use by emergency medical personnel or first responders dealing with large numbers of exposed individuals in mass casualty situations.

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[End of Amendment No. 0005]